IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARTHROCARE CORPORATION, Plaintiff, v. SMITH & NEPHEW, INC. Defendant.	
SMITH & NEPHEW, INC., Counterclaim Plaintiff, v. ARTHROCARE CORPORATION, AND ETHICON, INC., Counterclaim Defendants.	C.A. No. 01-504-SLR

SMITH & NEPHEW'S REPLY BRIEF IN SUPPORT OF ITS RULE 50(b) MOTION FOR JUDGMENT AS A MATTER OF LAW

Dated: August 14, 2003

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TABLE OF CONTENTS

Page

I. INTRODUCTION 1

II. ARGUMENT 1

A. The Accused Products Do Not Infringe the Asserted Claims 1

1. The Accused Products Do Not Infringe the '882 Patent 1

2. The Accused Products Do Not Infringe the '536 Patent 3

3. The Accused Products Do Not Infringe the '592 Patent 5

4. No Contributory Infringement or Inducement 7

5. Infringement Issues ArthroCare Failed to Prove at Trial 8

B. The Patents-In-Suit Are Invalid 9

1. Smith & Nephew's Rights Under Rule 50 Were Preserved 9

2. The PTO Granted Smith & Nephew's Reexamination Requests 10

3. The Asserted Claims of the '536 Patent Are Invalid 11

a. Anticipation by the Pao '499 Patent 11

b. Anticipation by the Doss '007 Patent 12

c. Anticipation by Roos '198 and the Elsässer Article 14

4. The Asserted Claims of the '882 Patent are Invalid 15

a. Anticipation by the Manwaring '138 Patent 15

b. Anticipation by the Slager Article 17

c. Lack of Enablement 18

5. The Asserted Claims of the '592 Patent Are Invalid 19

a. Anticipation by the Doss '007 Patent 19

TABLE OF CONTENTS (cont'd)

Page

b. Anticipation by the Slager Article 20

III. CONCLUSION 21

TABLE OF AUTHORITIES

Page(s)

CASES

Acosta v. Honda Motor Co.,
717 F.2d 828 (3d Cir. 1983) 10

Duro-Last, Inc. v. Custom Seal, Inc.,
321 F.3d 1098 (Fed. Cir. 2003) 10

Laborers' Pension Fund v. A&C Environmental, Inc.,
301 F.3d 768 (7th Cir. 2002) 9

Mahurkar v. C.R. Bard, Inc.,
79 F.3d 1572 (Fed. Cir. 1996) 17

Motorola, Inc. v. Interdigital Tech. Corp.,
930 F. Supp. 952 (D. Del. 1996)
rev'd in part on other grounds 121 F.3d 1461 (Fed. Cir. 1997). 9, 10

Ryco, Inc. v. Ag-Bag Corp.,
857 F.2d 1418 (Fed. Cir. 1988) 8

Schering Corp. v. Geneva Pharm., Inc.,
2003 WL 21767852 (Fed. Cir. Aug. 1, 2003) 13, 14

State Industrial, Inc. v. A.O. Smith Corp.,
751 F.2d 1226 (Fed. Cir. 1985) 8

Superior Fireplace Co. v. Majestic Prods. Co.,
92 F.Supp.2d 1001 (C.D. Cal. 2000),
aff'd in relevant part, 270 F.3d 1358 (Fed. Cir. 2001). 1, 2, 3, 4

Tandon Corp. v. U.S. International Trade Commission,
831 F.2d 1017 (Fed. Cir. 1987) 4, 6, 7

Ultradent Products, Inc. v. Life-Like Cosmetics, Inc.,
127 F.3d 1065 (Fed. Cir. 1997) 12

University of Rochester v. G.D. Searle & Co.,
249 F.Supp.2d 216 (W.D.N.Y. 2003) 19

Verdegaal Brothers, Inc. v. Union Oil Co. of Cal.,
814 F.2d 628 (Fed. Cir. 1987) 13

Wilburn v. Maritrans GP Inc.,
139 F.3d 350 (3d Cir. 1998) 2

Wilson Sporting Goods v. David Geoffrey & Assocs.,
904 F.2d 677 (Fed.Cir.1990), *overruled in part on other grounds*
by Cardinal Chem. Co. v. Morton Int'l, 508 U.S. 83 (1993). 9, 10

TABLE OF AUTHORITIES (c nt'd)

Page(s)

STATUTES AND OTHER AUTHORITIES

37 C.F.R. 1.555 ..... 16, 17, 20, 21

Fed. R. Civ. P. 50(b)(2)(B) 9

Fed. R. Evid. 701 2

I. INTRODUCTION

ArthroCare's Answering Brief fails to rebut Smith & Nephew's showing that JMOL should be entered in its favor on the following issues:

- the '882 certificate of correction is invalid;
- the accused products do not infringe any of the patents-in-suit;
- Smith & Nephew does not contribute to or induce infringement of the patents-in-suit;
- Smith & Nephew does not infringe under the doctrine of equivalents, non-suction Saphyre probes do not infringe claim 54 of the '882 patent, and Smith & Nephew does not directly infringe the '882 or '592 patents;
- the claims of the patents-in-suit are anticipated by various references; and
- the claims of the '882 patent are not enabled.

The evidence at trial, including the testimony of ArthroCare's own witnesses, supports Smith & Nephew's position on these issues. Further, since filing its Opening Brief, Smith & Nephew has learned that the PTO has granted its requests for reexamination of the patents-in-suit. These reexamination requests were based on virtually the same invalidity evidence that Smith & Nephew presented at trial, thus confirming that the jury was misled and that its verdict is incorrect. Thus, the Court should grant JMOL in favor of Smith & Nephew on these issues.

II. ARGUMENT

A. The Accused Products Do Not Infringe the Asserted Claims

1. The Accused Products Do Not Infringe the '882 Patent

ArthroCare has failed to overcome Smith & Nephew's showing that the certificate of correction which broadened claim 1 of the '882 patent was invalid, and thus, that there was no infringement of the '882 patent.[1] Smith & Nephew's Opening JMOL brief showed that the

[1] As set forth in our New Trial Motion, Smith & Nephew continues to maintain that the validity of the certificate of correction is an issue of law for the Court, and not for the jury (D.I. 456 at 27-30). This was also Smith & Nephew's position before trial (D.I. 246 at 35-37). ArthroCare itself also argued that it was an issue of law for the Court (D.I. 335 at 157) However, since the Court submitted the issue to the jury, Smith & Nephew has also shown that the certificate is invalid considering the evidence adduced at trial.

certificate of correction was invalid by the clear and convincing evidence introduced at trial, including the testimony of Dr. Goldberg, Mr. Raffle, and the '882 prosecution history (D.I. 459 at 14-19), under *Superior Fireplace Co. v. Majestic Prods. Co.*, 270 F.3d 1358 (Fed. Cir. 2001). Under *Superior Fireplace*, a broadening certificate of correction is only valid "where it is ***clearly evident*** from the specification, drawings, and prosecution history how the error should appropriately be corrected." *Id.* at 1372.[2] No reasonable juror could determine that the corrections made in the '882 certificate were "clearly evident" based on that record, particularly since the specification (*e.g.*, JTX-2 at cols. 3-5, 7-9, 11-12, 15, 20-23), drawings (*e.g.*, Figs. 15, 17, 19-22), and prosecution history (*e.g.*, amendment to claim 52 (DTX-306 at 204-05) and examiner's statement (DTX-306 at 222)) all supported the use of the term "active electrode" in claim 1 of the uncorrected '882 patent.[3]

ArthroCare complains that Smith & Nephew failed to introduce "expert testimony" about the certificate. (D.I. 467 at 18). But ArthroCare has not cited any case that suggests that this is a matter for expert testimony, and we are aware of none. Certainly there was no such expert testimony in *Superior Fireplace*—in fact, the district court expressly ***disavowed*** the use of any extrinsic evidence beyond the patent file itself. *Superior Fireplace Co. v. Majestic Prods. Co.*, 92 F.Supp.2d 1001, 1008-9 (C.D. Cal. 2000), *aff'd in relevant part,* 270 F.3d 1358 (Fed. Cir. 2001).

ArthroCare also argues that the trial testimony of Mr. Raffle, the patent's prosecutor, about his intent was sufficient to uphold the validity of the certificate. (D.I. 467 at 19). But *Superior Fireplace* clearly says that such intent is not relevant. *Id.* at 1375. Thus, no reasonable juror could have properly relied on Mr. Raffle's testimony about his intent. ArthroCare also points out that Mr. Raffle testified that there was an incorrect antecedent basis in the uncorrected claim. (D.I. 467 at 19). But the Federal Circuit explained in *Superior Fireplace* that an

[2] Emphasis added here and throughout, unless otherwise noted.

[3] Smith & Nephew also introduced the pre-litigation report of Mr. Heim (PX-75), who was one of skill in the art (D.I. 414 at 933-34), which shows that the use of the term "active electrode" in claim 1 of the '882 patent was not a "clearly evident" error. (*See* PX-75 at 24-25). *See Wilburn v. Maritrans GP Inc.*, 139 F.3d 350, 356 (3d Cir. 1998) (holding that a lay witness can offer opinion testimony if the witness possesses sufficient and relevant knowledge or experience).

antecedent error merely indicates that one of the limitations includes a mistake, but "does not indicate which is mistaken." *Id.* at 1362, 1373. And other than Mr. Raffle's irrelevant testimony, ArthroCare offered no other evidence to rebut the evidence offered by Smith & Nephew.[4]

Thus, JMOL should be entered that the '882 certificate of correction which broadened claim 1 is invalid, and that there is no infringement of the '882 patent.

2. The Accused Products Do Not Infringe the '536 Patent

ArthroCare has also failed to rebut Smith & Nephew's showing that it should be granted JMOL that the accused products do not infringe the asserted claims of the '536 patent. As shown in Smith & Nephew's Opening Brief, ArthroCare introduced ***no*** evidence that the accused probes are part of an "electrosurgical system" as construed by the Court: "an assemblage or combination of things or parts ***forming a unitary whole,***" which includes "an electrically conducting fluid supply." (D.I. 459 at 6-10).[5] ArthroCare has not shown otherwise, and, in fact, the evidence ArthroCare cites in its opposition actually proves that Smith & Nephew does not infringe.

As described in the '536 patent, the integral fluid supply is included as part of the "unitary whole" system so that the invention can be used in open surgical procedures. The patent explicitly describes the invention as one for performing electrosurgery "***without*** requiring the tissue ***to be submerged*** in an electrically conducting irrigant, such as isotonic saline." (JTX-1 at col.3, lines 12-18). Thus, the patent says the invention is "particularly effective in dry environments (*i.e.*, the tissue ***is not submerged in fluid***)." (*Id.* at col. 3, lines 37-41). Yet, despite the patent's clear disavowal of submerging the device in fluid, the only evidence ArthroCare

[4] None of ArthroCare's other arguments has any merit. *E.g.*, ArthroCare argues that Mr. Raffle was not motivated to sue Ethicon since he did not amend claim 26. (D.I. 467 at 20). But in our Reply Brief on the inequitable conduct issue, we showed that ArthroCare did not need to amend claim 26 to sue Ethicon. (D.I. 464 at 12-13). ArthroCare also tries to distinguish a portion of *Superior Fireplace* by arguing that there was no reason to respond to the examiner's statement of reasons for allowance since the claims had been allowed. (D.I. 467 at 20). But that argument makes no sense, since the claims in *Superior Fireplace* were also allowed at the same time that the examiner issued his amendment which contained the alleged error. 270 F.3d at 1363.

[5] Contrary t ArthroCare's argument (D.I. 467 at 7-8), Smith & Nephew did not argue that there had to be a fluid path within the probe, alth ugh that certainly would be one way to have a "unitary whole" system that included a fluid supply.

points to is evidence that the Smith & Nephew devices work when submerged in fluid, *e.g.*, "the tissue was shown completely submerged under saline." (D.I. 467 at 11). Indeed, ArthroCare concedes that the accused probes are ***contraindicated*** for any procedure other than arthroscopy, in which the device will necessarily be ***submerged*** in fluid. (D.I. 467 at 11, 21).

Further, when the accused devices are used, the fluid is supplied to the joint by a wholly separate means, such as an IV bag or a separate system like the IntelliJet system. Such separate fluid supply is not integral with or otherwise part of a "unitary whole" with the probe, but rather is a standard fluid supply used in all arthroscopic surgeries. Thus, ArthroCare's evidence that the accused devices will only work when submerged in conductive fluid—which is supplied by a completely separate means such as an IV bag—falls far short of proving that they are part of a "unitary whole" electrosurgical system that includes a conductive fluid supply.[6]

ArthroCare also argues that claim differentiation between claims 1 and 45 shows that claim 45 does not require that the fluid travel through a fluid path within the probe. (D.I. 467 at 8 n.1). However, "[w]hether or not claims differ from each other, one can not interpret a claim to be broader than what is contained in the specification and claims as filed." *Tandon Corp. v. U.S. Int'l Trade Comm'n*, 831 F.2d 1017, 1024 (Fed. Cir. 1987). As the Court in *Tandon* held:

> [P]ractice has long recognized that "claims may be multiplied ... to define the metes and bounds of the invention in a variety of different ways." Thus two claims which read differently can cover the same subject matter.

Id. at 1023 (citing *Bourns, Inc. v. United States*, 537 F.2d 486, 492 (Ct. Cl. 1976)) (internal citation omitted).[7] Thus, ArthroCare did not rebut Smith & Nephew's *prima facie* case that the accused products are not part of an "electrosurgical system" which includes a "fluid supply" as construed by this Court. Therefore, the Court should grant JMOL of no infringement.

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[6] ArthroCare's argument that Dr. Taylor described the *in vitro* experiment in the Slager Article as an electrosurgical system is inapposite. First, Dr. Taylor asserted the Slager Article only against the '882 and '592 patents, neither of which claim an "electrosurgical system" like the '536 patent. Further, while Slager might describe a type of system, Dr. Taylor never said that it was an "electrosurgical system" as that term was construed by the Court.

[7] In any event, claims 1 and 45 clearly have a different scope. *E.g.*, claim 45 includes a power supply; whereas, claim 1 does not.

3. The Accused Products Do N t Infringe the '592 Patent

ArthroCare has also failed to rebut Smith & Nephew's showing that it should be granted JMOL that the accused products do not infringe the asserted claims of the '592 patent. As shown in Smith & Nephew's Opening Brief, ArthroCare's evidence was based on the claim construction that ArthroCare proposed in its summary judgment briefs—which the Court rejected.[8] (D.I. 459 at 10-13). But ArthroCare introduced ***no*** evidence of infringement under the Court's claim construction: "the return electrode is not to contact the body ***at all during the performance of the claimed method***" (D.I. 353 at 2) (emphasis in original).

The evidence at trial showed that the return electrodes of the accused products touch the body structure on a nearly continuous basis during use. ArthroCare does not dispute this. Instead, it defends the jury's verdict by arguing that "there are times" when the return electrode does not contact tissue. (D.I. 467 at 12-14). However, ArthroCare improperly focuses on only a portion of one claim step, while ignoring the others. In doing so, ArthroCare has failed to show that the return electrode is not in contact with the body "***at all during the performance of the claimed method***" as the Court's construction requires. Instead, ArthroCare twists the Court's ruling that the claimed method does not contain any time limitations and argues that if during the applying energy step of the method the return electrode does not touch for a split second, there is infringement. ArthroCare's argument makes no sense—it takes the words "***at all***" out of the Court's claim construction—and is wrong.

First, as pointed out in Smith & Nephew's Opening Brief (D.I. 459 at 11-12), ArthroCare's argument completely ignores the first step of the claimed method: "positioning an electrode terminal into at least close proximity with the target site in the presence of an electrically conductive fluid." (JTX-3 at claim 1; *see also* claim 23). As was seen in the various sales-training videos shown during trial, during the portions of the procedure that the energy was not being applied, the first step of the claimed method was being practiced—the probe was being

[8] The Court rejected ArthroCare's claim construction in its Memorandum Opinion of April 9, 2003 (D.I. 353 at 6-7), and ArthroCare's argument that it did not propose a claim construction for the Court to reject (D.I. 467 at 14, n.5) is incorrect.

positioned—and the return electrode often touched the tissue during that positioning step. (DTX-315, 316). The positioning step is also part of the claimed method, and ArthroCare cannot ignore it.

Second, ArthroCare cannot take a split second out of the claimed method and ignore the rest of the time the method is being performed. While the Court did rule that there was no time limitation to the method, it also instructed the jury that "the claimed method is performed when each of the three steps of the claim has been ***completed***." (D.I. 418 at 1718). Thus, as pointed out in our Opening Brief (D.I. 459 at 12-13), the method is not "completed" until the energy is turned off. At that point, the method starts over again by the surgeon "positioning [the] electrode terminal into at least close proximity with the target site." So, contrary to ArthroCare's argument (D.I. 467 at 16), if the return touches the tissue while the energy is on, there can be no infringement even if there had been no contact for the first 3 seconds. This is not a time limitation as ArthroCare asserts, but rather follows the Court's construction that "the claimed method is performed when each of the three steps of the claim has been ***completed***."

ArthroCare's argument that the design of the probes somehow proves that the return does not touch tissue (D.I. 467 at 17) is also wrong. First, this argument is inconsistent with its argument that Smith & Nephew warns surgeons to avoid return electrode contact. (*Id.* at 13). If the probes were designed so the return would not contact tissue, why would Smith & Nephew need to warn surgeons to avoid contact?[9] Further, the evidence demonstrates that the probes were not designed to avoid return electrode contact. For example, Kate Knudsen testified that the Saphyre was designed to have the return electrode as close as possible to the active electrode so that the return would be in the surgeon's view to monitor the return electrode contact with tissue. (D.I. 414 at 963-64). This is confirmed by the Instructions for Use ("IFU") for the Saphyre, which only warn to avoid contact with "non-targeted tissue" (PX-381), since contact with target

[9] In any event, ArthroCare has no persuasive evidence that Smith & Nephew actually warns doctors in this way. All ArthroCare's "evidence" shows is how to hold the Saphyre to ensure optimal bubble evacuation (PX 324 at ORA 65090), and to make sure enough fluid is present around the ElectroBlade and Control RF to ensure that the return does not cause a tissue effect when it touches (D.I. 415 at 1023-25).

tissue was expected. Similarly, Karen Drucker testified that the ElectroBlade was designed with a large return since they "knew that the return would, in fact, contact tissue." (D.I. 415 at 1024).

Dr. Goldberg's testimony also corroborates the fact that the probes were not designed to avoid contact with tissue. For example, Dr. Goldberg testified "very clearly there is occasional contact frequently ..." (D.I. 411 at 423). Dr. Goldberg then goes on to contradict himself with the claim that the "probe is designed to enable [there] not being contact." (*Id.*). Clearly, if there is "contact frequently," the probes were not designed to avoid contact. Also, Dr. Goldberg tried to make much of the fact that the return electrodes of the Saphyre and Control RF are on a different plane, below the active electrode. (D.I. 411 at 397 and 424). However, if this is evidence of no contact, then the ElectroBlade return must contact tissue because the return is on a plane spaced ***above*** the active electrode. (PX-113-A; PX-335). Finally, if the probes were designed to avoid contact, ArthroCare would not have to rely on still images from the sales training videos (D.I. 467 at 16, n.6), but rather could have easily shown no contact while the videos were playing.

Thus, ArthroCare did not rebut Smith & Nephew's *prima facie* case that the return electrode of the accused products contacts tissue during performance of the claimed method as construed by the Court, and the Court should grant JMOL of no infringement.

4. No Contributory Infringement or Inducement

ArthroCare has also failed to prove that Smith & Nephew contributorily infringes or induces infringement. ArthroCare focuses on its alleged copying theory and its contention that the accused products were designed to infringe. (D.I. 467 at 21, 25). Both arguments must fail.

First, as discussed in our New Trial Brief (D.I. 456 at 17-24), ArthroCare's focus on its alleged copying case was prejudicial to Smith & Nephew. Since the trial is bifurcated, Smith & Nephew could not rebut ArthroCare's "evidence" to show no copying occurred. Further, Smith & Nephew's awareness of ArthroCare's patents and its review of ArthroCare's devices alone do not prove that the devices were copied or designed to infringe. *See, e.g., State Indus., Inc. v. A.O. Smith Corp.*, 751 F.2d 1226, 1235-36 (Fed. Cir. 1985) ("Conduct such as [defendant's], involving

keeping track of a competitor's products and designing new and possibly better or cheaper functional equivalents is the stuff of which competition is made ..."); *see also Ryco, Inc. v. Ag-Bag Corp.*, 857 F.2d 1418, 1435 (Fed. Cir. 1988) ("[T]he incentive to design around a patent is a positive result of the patent system."). Thus, none of ArthroCare's evidence proves that Smith & Nephew intended to infringe, and there can be no inducement.

Also, as discussed above, the accused products cannot be designed to infringe because they are contraindicated for any use outside arthroscopy. The patents-in-suit are specifically directed to devices that can be used in a dry environment; *i.e.*, outside arthroscopy. (*See, e.g.*, JTX-1 at col. 3, lines 26-30). Since the products cannot be used outside arthroscopy, they cannot be designed to infringe. ArthroCare's argument that since electrically conducting fluid is present in arthroscopy it must infringe is clearly misleading. Similarly, as discussed above, the return electrodes were not designed to not contact tissue (D.I. 414 at 963-64, D.I. 415 at 1024; PX-113-A; PX-335), but rather to allow tissue contact with minimal effect. Since the return electrodes were designed to allow contact, they could not have been designed to infringe.

Moreover, since the accused products work when the return electrodes touch tissue, they have substantial non-infringing uses. Indeed, taking Mr. Bobrow's example from his closing argument, where for three seconds the return electrode is not in contact and then for one second it is (D.I. 417 at 1580), would mean that the device was not infringing—even under ArthroCare's rejected claim construction (discussed above)—25% of the time. Such a non-infringing use is clearly substantial, and not "occasional and aberrant" as ArthroCare suggests. (D.I. 467 at 22).

Thus, ArthroCare did not rebut Smith & Nephew's *prima facie* showing of no contributory infringement and no inducement, and the Court should grant JMOL on this issue.

5. Infringement Issues ArthroCare Failed to Prove at Trial

ArthroCare's Opposition does not substantively challenge Smith & Nephew's right to JMOL under Fed. R. Civ. P. 50(b)(2)(B) that: (1) there is no infringement under the doctrine of equivalents, (2) the non-suction Saphyre probes do not infringe claim 54 of the '882 patent and (3) Smith & Nephew does not directly infringe the '882 and '592 patents. ArthroCare's

procedural argument that these issues cannot be resolved by JMOL (D.I. 467 at 6) is refuted by the clear language of the rule itself. Rule 50(b)(2)(B) specifically states that "the court may[,] if no verdict was returned[,] ... direct entry of judgment as a matter of law." No verdict was returned on these issues because ArthroCare, although it raised the issues before trial, failed to present any evidence to support its accusations. ArthroCare should be precluded from raising these issues in the future, and the Court should enter JMOL for Smith & Nephew's on these issues.

B. The Patents-In-Suit Are Invalid

1. Smith & Nephew's Rights Under Rule 50 Were Preserved

Contrary to ArthroCare's arguments (D.I. 467 at 26), the Court clearly preserved Smith & Nephew's rights under Fed. R. Civ. P. 50(a). The Court can preserve the parties' rights and submit the matter to the jury without requiring a detailed Rule 50(a) motion and without affecting the parties' rights under Rule 50(b). *Motorola, Inc. v. Interdigital Tech. Corp.*, 930 F. Supp. 952, 961 (D. Del. 1996) *rev'd in part on other grounds* 121 F.3d 1461 (Fed. Cir. 1997); *see also Wilson Sporting Goods v. David Geoffrey & Assocs.*, 904 F.2d 677, 683 (Fed.Cir.1990) *overruled in part on other grounds by Cardinal Chem. Co. v. Morton Int'l*, 508 U.S. 83 (1993); *Laborers' Pension Fund v. A&C Environ., Inc.*, 301 F.3d 768, 776-77 (7th Cir. 2002).

Here, when Smith & Nephew moved for JMOL during trial, the Court indicated that it was not interested in a detailed argument, instructing the parties that all of their rights were reserved. Smith & Nephew first moved for JMOL at the close of ArthroCare's evidence. (D.I. 415 at 1161). Smith & Nephew then renewed its motion at the close of all the evidence, to which the Court replied "***All*** such motions are reserved." (D.I. 417 at 1549). Then, just prior to the jury charge, Smith & Nephew again renewed its motion. (D.I. 418 at 1700). In response, the Court said, "***All*** your rights are reserved and my decisions are reserved as well." (*Id.*).

As can be seen from these exchanges, the Court cut-off any further discussion and explicitly reserved ***all*** of both parties' rights as to JMOL motions. This is identical to what happened in *Motorola*, in which the movant made a barebones motion under Rule 50(a):

> The Court made clear that it did not require or desire additional argument at the time the motion was made, and it would be unfair to penalize ITC for acceding to the Court's wishes. The Court will rule on ITC's JMOL motion.

930 F. Supp. at 961; *see also Wilson Sporting Goods Co.*, 904 F.2d at 683. Thus, Smith & Nephew's rights under Rule 50 were properly preserved.[10]

Moreover, ArthroCare has failed to show any prejudice from any lack of a more detailed Rule 50(a) motion, or that the spirit of the rule has been offended.[11] The purpose of Rule 50(a) is the "avoidance of surprises and tactical victories at the expense of substantive interests." *Acosta v. Honda Motor Co.*, 717 F.2d 828, 832 (3d Cir. 1983) (quoting *Wall v. United States*, 592 F.2d 154 (3d Cir. 1979)). Rule 50(a) protects that spirit by requiring notice to afford the other party the opportunity to cure possible technical defects in its proof. *Id.* at 831

ArthroCare was fully aware of Smith & Nephew's invalidity defenses and made a deliberate decision to not put on ***any*** rebuttal case on invalidity. Instead, ArthroCare chose only to cross-examine Smith & Nephew's experts and called only one rebuttal witness to support its copying theory (D.I. 417 at 1544-48) before resting (D.I. 417 at 1548). Further, ArthroCare has not shown any prejudice or that it would have proceeded any differently if Smith & Nephew had presented a more detailed JMOL motion.

Thus, ArthroCare's argument that Smith & Nephew's Rule 50 rights were not preserved has no merit.

2. The PTO Granted Smith & Nephew's Reexamination Requests

As discussed in Smith & Nephew's Reply Brief in Support of Its Inequitable Conduct Case, the PTO recently granted Smith & Nephew's requests to reexamine each of the patents-in-suit. (D.I. 464 at 1; *see also* Exs. A, B and C attached to the Declaration of Eugene Joswick in Support of this Brief, hereafter "Joswick Dec."). The PTO's granting of the requests supports

[10] None of the cases cited by ArthroCare address the issue of the Court's ability to reserve the issues and the parties' rights.

[11] Even *Duro-Last, Inc. v. Custom Seal, Inc.*, 321 F.3d 1098, 1106 (Fed. Cir. 2003), a case cited by ArthroCare, recognized that "[a] liberal reading of the rule may be appropriate in some circumstances, such as when the failure is largely a technical one, and no prejudice results."

Smith & Nephew's contention that the jury was misled by ArthroCare during trial and that its verdict of validity was against the great weight of the evidence. For example, as the Order Granting the Request to reexamine the '592 patent points out: "Roos '198 discloses an electrically conducting fluid in Claim 1. The teaching of an electrically conducting fluid by Roos '198 was not considered in the prosecution of the application, which became the Eggers et al. patent." (Joswick Dec Ex. C at 3). This same "teaching" was presented to the jury during trial but was ignored despite the lack of any meaningful rebuttal by ArthroCare. The Court should consider these new reexamination determinations in evaluating Smith & Nephew's evidence supporting its request for JMOL on the anticipation issues.[12]

3. The Asserted Claims of the '536 Patent Are Invalid

a. Anticipation by the Pao '499 Patent

ArthroCare has failed to rebut Smith & Nephew's showing that it should be granted JMOL of anticipation in view of the Pao '499 patent.

ArthroCare now argues that its cross-examination of Dr. Taylor was directed to the "current flow path" limitation of claim 45, rather than the "minimize direct contact" limitation of claim 47. (D.I. 467 at 29). ArthroCare's argument is curious since its questions to Dr. Taylor were clearly about "contact." But even if these questions somehow related to current flow path, the cross-examination did not overcome Smith & Nephew's *prima facie* case. The testimony from Dr. Taylor to which ArthroCare refers was clearly directed to only one embodiment described in the Pao '499 reference which discloses placing both electrodes in contact with tissue (D.I. 416 at 1408-10):

> Q. And so, if you're interpreting the outer electrodes as being a return, that means there the return electrode as described in this paragraph ***is in contact*** with the tissue; right?
>
> A. Yes. And ***this is one description how it could be used, but there are other descriptions where the outer electrode and return electrode does not contact tissue.***
>
> * * *

[12] The fact that the PTO has granted these reexamination requests negates ArthroCare's argument that Smith & Nephew had a "more difficult" burden because the PTO had previously considered these references. (D.I. 467 at 28-29, 31).

> Q. So in this description of its use, what it's essentially saying is that you put ***the active and the return in contact*** with tissue and then the current then will flow between those two electrodes through the tissue; right?
>
> A. And this is one way, yes. The answer to your question is yes, and ***this is one way you use the device. It's not the only way.***

However, ArthroCare's reliance on a different embodiment does not rebut Smith & Nephew's *prima facie* case based on the anticipating embodiments disclosed in the Pao '499 patent. *See Ultradent Prods., Inc. v. Life-Like Cosmetics, Inc.*, 127 F.3d 1065, 1068 (Fed. Cir. 1997).

Indeed, the Pao '499 patent itself explicitly and inherently discloses that current will flow through the electrically conductive fluid. First, the current flow through the saline is explicitly disclosed. (DTX-21 at col. 7, lines 63-67). Second, the Pao '499 patent teaches that saline is introduced through the active electrode. (*Id.*). Since saline is an electrically conductive fluid, the current will necessarily flow through the saline between the active and return electrodes. Dr. Goldberg recognized this inherent property when discussing the accused products:

> And again, because it's electrically conductive fluids, when...the high-frequency generator, is activated, there will be current flow path between the active and the return.

(D.I. 411 at 406; *see also* D.I. 411 at 398 and 412). The PTO also recognized this in granting Smith & Nephew's reexamination request based on the Pao '499 patent: "Requestor presents materially new arguments with respect to Pao '499 disclosure of introducing saline to the electrosurgical site and the saline's inherent property of conduction." (Joswick Dec. Ex. A at 4).

Thus, ArthroCare did not rebut Smith & Nephew's *prima facie* case of anticipation based on the Pao '499 patent, and the Court should grant JMOL on this issue.

b. Anticipation by the Doss '007 Patent

ArthroCare has also failed to rebut Smith & Nephew's showing that it should be granted JMOL of anticipation in view of the Doss '007 patent.

As discussed in our Opening Brief, the Doss '007 patent discloses a return electrode under the Court's claim construction: "an electrode having a larger area of contact than an active electrode, thus affording a lower current density." (D.I. 459 at 26-28). ArthroCare's argument

that Doss '007 does not disclose a return electrode disregards the Court's claim construction of return electrode and focuses only on the definition of active electrode. (D.I. 467 at 30). ArthroCare argues that since the outer electrode has some tissue effect, it must be an active electrode. But as we showed in our Opening Brief (D.I. 459 at 27-28), ArthroCare ignored the Court's admonishment during trial that it needed to show there was "no difference" between the active and return electrodes. (D.I. 416 at 1389). Even now, in its Opposition Brief, ArthroCare does not argue that there is no difference between the two electrodes. ArthroCare's argument that the outer electrode has a tissue effect, and thus is an active electrode (D.I. 467 at 30), is clearly contrary to the Court's claim construction and should be rejected.[13]

As also discussed in our Opening Brief, the Doss '007 patent discloses a connector at the proximal end of the device under the Court's claim construction: "a structure that electrically links the electrode terminal to the high frequency power supply." (D.I. 459 at 29-30). Once again ArthroCare focuses on the fact that the location of the connector is not explicitly disclosed. (D.I. 467 at 30). However, this is irrelevant because the location is inherently disclosed.[14] For example, Figure 7 shows both electrodes passing out the proximal (top) end of the device (DTX-17 at Fig. 7), which is the only place a connector could be located to "link the electrode terminal to the high frequency power supply." Further, and contrary to ArthroCare's argument, a single wire passing through the proximal end of the device from the active electrode to the power supply satisfies the Court's claim construction of "connector." There is no requirement in the Court's claim construction that the connector not be a conductor, or that it be a separate structure which is located only near the proximal end of the shaft, as ArthroCare argues.[15]

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[13] ArthroCare's argument about Dr. Taylor's deposition testimony is also unavailing. (D.I. 467 at 30-31). Even if the jury were to disregard that testimony, the jury cannot disregard the explicit disclosure in the reference (DTX-17 at Figs. 7 and 8) and this Court's claim construction. *Verdegaal Bros., Inc. v. Union Oil Co. of Cal.*, 814 F.2d 628, 632 (Fed. Cir. 1987).

[14] *See, e.g., Schering Corp. v. Geneva Pharm., Inc.*, 2003 WL 21767852 at *4 (Fed. Cir. Aug. 1, 2003) (a prior art reference need not supply an "express description of any part of the claimed subject matter" to anticipate).

[15] Had there been any such requirement, the accused products would not have a "connector."

Accordingly, ArthroCare did not rebut Smith & Nephew's *prima facie* case of anticipation based on the Doss '007 patent, and the Court should grant JMOL on this issue.

c. Anticipation by Roos '198 and the Elsässer Article

ArthroCare has also failed to rebut Smith & Nephew's showing that it should be granted JMOL of anticipation in view of the Roos '198 patent and the Elsässer Article.

ArthroCare first argues that the Roos '198 patent and the Elsässer Article do not disclose a connector near the proximal end of the shaft. (D.I. 467 at 31-33). With respect to the Elsässer Article, ArthroCare does not deny that it failed to ask Dr. Taylor a single question or present any evidence to contradict the disclosure in the Elsässer Article. Instead, ArthroCare says that Dr. Taylor identified no disclosure of a connector in the Article. (*Id.* at 31). ArthroCare is clearly wrong, since Dr. Taylor said "the one that is shown is right there." (D.I. 416 at 1298).[16] Moreover, Figure 9 of Elsässer clearly shows connectors at the proximal end of the shaft, and does not show anything else that could be used to connect the electrodes to the generator. Thus, one of these connectors must necessarily be used to connect the active electrode to the generator.

With respect to the Roos '198 patent, ArthroCare mischaracterizes the passages that Smith & Nephew quotes in its Opening Brief. ArthroCare argues that the first passage quoted, regarding the leads 16, "discusses a cable leading to the return electrode." (D.I. 467 at 32). ArthroCare is wrong. Figures 7 and 8, which the quoted passage describes, clearly show that the leads 16 are connected to the active electrode (12) and not the return electrode (11). The cable leading to the return electrode is labeled 14, not 16. (DTX-11 at col. 7, lines 5-8).

ArthroCare also argues that the Roos patent and Elsässer Article do not disclose electrically conducting fluid. (D.I. 467 at 33-34). In doing so, ArthroCare continues to make the same tortured arguments in an attempt to avoid the explicit disclosures in both references. For example, ArthroCare points to an irrelevant patent issued some ten years later, to the fact that

[16] ArthroCare argues that because Dr. Taylor also used the word "connector" when describing a fluid connection in the Pao '499 patent, the jury was entitled to disregard any testimony he gave on connectors. (D.I. 467 at 32). This argument borders on the frivolous, since Dr. Taylor clearly described the connector in the Elsässer Article as an electrical connector. (D.I. 416 at 1298).

saline or ringers lactate is not explicitly recited, and the fact that Mr. Roos used the same generic term ("washing liquid") for the fluid used with monopolar and bipolar procedures,[17] all in an attempt to side-step the explicit disclosures in claim 1 of the Roos patent and its file history.

ArthroCare's argument that claim 1 of the Roos patent disclosed non-conductive fluid since non-conductive fluids will conduct some electrical current (D.I. 467 at 34) is nonsense. Roos claim 1 says that the purpose of the liquid was "***to provide*** electrical conductance," which clearly meets the Court's definition of "any fluid that ***facilitates*** the passage of electrical current." (D.I. 353). Further, the Roos prosecution history calls the washing liquid an "electrical conductor" and says "the washing fluid would conduct electrical current just as the tissue fluid [*e.g.*, blood] and the tissue itself of the human body." (DTX-321, 8/12/77 Amendment at p. 7). The PTO also recognized that the Roos '198 patent discloses an electrically conductive fluid in granting Smith & Nephew's new reexamination request. (Joswick Dec. Ex. A at 3).

ArthroCare also argues that Smith & Nephew's quote from the Elsässer Article does not support a disclosure of an electrically conductive fluid. (D.I. 467 at 34, n.12). However, in so arguing, ArthroCare misleadingly cropped the following sentence out of the passage quoted by Smith & Nephew: "***The current flows*** directly from the cutting loop to the neutral electrode ***through the adjacent tissue to be cut and the irrigation liquid.***" (DTX-59B at 4 and D.I. 459 at 32). As this sentence shows, the Elsässer Article explicitly discloses electrically conductive fluid.

Thus, ArthroCare did not rebut Smith & Nephew's *prima facie* case of anticipation based on the Roos '198 patent and Elässer Article, and the Court should grant JMOL on this issue.

4. The Asserted Claims of the '882 Patent are Invalid

a. Anticipation by the Manwaring '138 Patent

ArthroCare has also failed to rebut Smith & Nephew's showing that it should be granted JMOL of anticipation in view of the Manwaring '138 patent. ArthroCare's argument is based on

[17] To this very day, electrically conductive saline is called "irrigation" liquid. (D.I. 416 at 1462).

the lack of explicit disclosure of UV photons in the Manwaring '138 patent, and that the suction disclosed is not sufficient to evacuate fluid generated at the target site. (D.I. 467 at 35-36).[18]

First, the undisputed testimony at trial shows that UV photons are inherently produced in the Manwaring '138 patent due to the operation of the laws of physics.[19] Dr. Taylor testified that a spark in aqueous solution will generate UV photons "because of the transition of the hydroxyl ion." (D.I. 416 at 1420). Dr. Manwaring also testified that sparking in water will produce UV photons. (D.I. 414 at 918-19). Moreover, this testimony is corroborated by the teaching of the '882 patent itself, which describes the production of UV photons from the "high electric field generated ... within the electrically conductive liquid." (*See* PX-2 at col. 4, lines 47-57). ArthroCare introduced no contrary evidence.[20]

Second, ArthroCare did not rebut the fact that the Manwaring '138 patent explicitly discloses evacuating fluid generated at the target site: "fluid ... could be sucked into or drawn up tube 28 to a sufficient elevation." (DTX-46 at col. 7, lines 26-31). In its Opposition, ArthroCare denies that it ever argued that ***all*** of the fluid had to be evacuated, after we pointed out that was not required by the claim. (D.I. 467 at 35-36). Now ArthroCare argues that some of the fluid would remain "in the ***vicinity***" of the tissue. (*Id.*). But this is the same argument under a different name. ArthroCare is still trying to read extraneous limitations into the claim, which only requires "evacuating" (and is met by Manwaring) and does not say anything at all about "removing" "from beyond the vicinity" of the tissue.

[18] ArthroCare also argues that Manwaring discloses sparking followed by vaporization. (D.I. 467 at 35). However, as Dr. Goldberg admitted, the claim requires vaporization ***and*** sparking, not vaporization ***then*** sparking. (D.I. 415 at 1087).

[19] ArthroCare is under a continuing duty to apprise the PTO of any litigation activity (Joswick Dec. Ex. B at 3; 37 C.F.R. 1.555), and must disclose the Skromme report to the PTO showing that the commercial embodiment of the Manwaring patent did in fact produce UV photons.

[20] ArthroCare now challenges Dr. Taylor's explanation that the production of UV photons was a matter of elementary college chemistry, by saying that he "could produce no college chemistry textbook ... that supported his position." (D.I. 467 at 35, n.14). But ArthroCare never asked him for such a college textbo k.

Moreover, the PTO recognized the validity of both of these arguments in granting Smith & Nephew's reexamination request based on the Manwaring '138 patent: "These teachings were not previously considered nor addressed in prior examinations of the patent. There is a substantial likelihood that a reasonable examiner would consider these teachings important in deciding whether or not the claims are patentable." (Joswick Dec. Ex. B at 3).

Thus, ArthroCare did not rebut Smith & Nephew's *prima facie* case of anticipation based on the Manwaring '138 patent, and the Court should grant JMOL on this issue.

b. Anticipation by the Slager Article

ArthroCare also failed to rebut Smith & Nephew's showing that it should be granted JMOL of anticipation in view of the Slager Article. ArthroCare has raised three arguments.

First, ArthroCare protests that the Slager Article only discloses applying energy to a piece of aortic tissue in a petri dish. (D.I. 467 at 36). As discussed in our Opening Brief, this is sufficient to meet the claim since Mr. Eggers' reduction to practice only involved experiments on chicken parts in a bowl. (D.I. 459 at 38). ArthroCare cites *Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572 (Fed. Cir. 1996), but that case actually supports Smith & Nephew's position. In *Mahurkar*, the patentee was attempting to pre-date a reference by showing a prior reduction to practice. *Id.* at 1578. The issue was whether the patentee's brittle prototype catheters met the "prevent[ing] the distal end of the catheter from traumatizing" the vessel limitation. *Id.* The court held they did, since the patentee "knew that his invention would become suitable for its intended purpose by simple substitution of a soft, biocompatible material." *Id.* The Slager Article meets all the limitations of the claim for the same reasons. Further, the ultimate "clinical" use of the device is explicitly disclosed. (DTX-65 at 1386). ArthroCare's argument is also undercut by Dr. Goldberg's testimony on infringement (D.I. 415 at 1088): "to determine what a device can and cannot do often requires scientific analysis outside of the body." If analysis outside the body is sufficient for infringement evaluations, it is also sufficient for invalidity.

Second, ArthroCare argues that the Slager Article does not explicitly disclose the production of UV photons. However, as discussed above with respect to the Manwaring '138

patent, any sparking in an aqueous solution (which is disclosed in Slager—*see* DTX 65 at 1384-85) will inherently produce UV photons by operation of the laws of physics.

Finally, ArthroCare says that Dr. Taylor admitted that the Slager Article does not explicitly disclose the location of the suction lumen for evacuating the fluid generated at the target site. (D.I. 467 at 37). However, this does not overcome the inherent disclosure in the Slager Article. Since Slager discusses the use of a suction technique to remove the gas bubbles that are locally produced at the active electrode (DTX-65 at 1383, 1386), the suction lumen would necessarily be adjacent the active electrode.

Moreover, the PTO has recognized the validity of these arguments in granting Smith & Nephew's reexamination requests based on the Slager Article: "These teachings were not previously considered nor addressed in prior examinations of the patent. There is a substantial likelihood that a reasonable examiner would consider these teachings important in deciding whether or not the claims are patentable." (Joswick Dec. Ex. B at 3).

Thus, ArthroCare did not rebut Smith & Nephew's *prima facie* case of anticipation based on the Slager Article. The Court should grant JMOL in Smith & Nephew's favor on this issue.

c. Lack of Enablement

ArthroCare failed to rebut Smith & Nephew's showing that the asserted claims of the '882 patent are not enabled, and thus JMOL in Smith & Nephew's favor is proper.

ArthroCare's main argument is that the '882 patent lists preferred ranges for many of the variables. (D.I. 467 at 39). However, the '882 patent itself notes that the invention only works "under optimal conditions." (JTX-2 at col. 10, lines 65-67). During trial, ArthroCare asked Dr. Taylor about seven of the listed variables. (D.I. 416 at 1436-1438).[21] Most of even the more preferred ranges for those variables are still quite broad; *e.g.*, voltage ranges of 100 to 400 volts, frequency of 50 to 400 kHz, active electrode contact area of 0.005 mm^2 to 0.5 mm^2, etc. These broad ranges for all the variables listed in the '882 patent result in hundreds, if not thousands, of

[21] Some of these limitation ranges were discussed in the table at page 43 of our Opening Brief, which sh ws how these preferred ranges would produce the Manwaring device.

possible combinations and permutations. Clearly, one would be required to perform extensive undue experimentation to determine exactly which combinations provided the required "optimal conditions" and which did not. *See, e.g., University of Rochester v. G.D. Searle & Co.*, 249 F.Supp.2d 216 (W.D.N.Y. 2003) (patent invalid for lack of enablement since it provided "precious little guidance" for "narrowing the range" of candidate compounds, and thus would require undue experimentation). Thus, the '882 patent is not enabled.

ArthroCare also argues that there was no basis for Dr. Taylor "to equate 'Coblation' with the claims of the '882 patent." (D.I. 467). This is simply incorrect. For example, Jean Woloszko, ArthroCare's V.P. of Research and Development, testified that "Coblation" is ArthroCare's term for conducting current through a conductive fluid and creating a glow discharge plasma to ablate tissue. (D.I. 415 at 1048-49). This is exactly what the '882 patent teaches happens when the so-called "optimal conditions" are realized. (*See* JTX-2 at col. 10, line 65 to col. 11, line 1). Thus, there was ample evidence for Dr. Taylor to equate the claims of the '882 patent with Coblation.

Accordingly, ArthroCare did not rebut Smith & Nephew's *prima facie* case of invalidity based on non-enablement, and the Court should grant JMOL on this issue.

5. The Asserted Claims of the '592 Patent Are Invalid

a. Anticipation by the Doss '007 Patent

ArthroCare has failed to rebut Smith & Nephew's showing that it should be granted JMOL of anticipation in view of the Doss '007 patent.

ArthroCare again argues that Doss does not disclose a return electrode. (D.I. 467 at 39). However, as discussed above, this argument fails because the outer electrode of the embodiment shown in Figures 7 and 8 is a return electrode under the Court's claim construction, which ArthroCare ignored.

ArthroCare also argues that the generator disclosed in the Doss '007 patent is not necessarily a sine wave generator, and if it is not, the voltage might not be in the range required by claims 21 and 42. (D.I. 467 at 39). But ArthroCare's speculation is unavailing, since Doss

clearly says that "***any*** radio-frequency current" having the specified characteristics "is suitable" (DTX-17 at col. 3, lines 30-38), and thus a sine wave is inherently included. Further, it was undisputed at trial that only sine wave generators were commercially available. (D.I. 416 at 1402).[22]

Thus, ArthroCare did not rebut Smith & Nephew's *prima facie* case of anticipation based on the Doss '007 patent, and the Court should grant JMOL on this issue.

b. Anticipation by the Slager Article

Finally, ArthroCare failed to rebut Smith & Nephew's showing that it should be granted JMOL of anticipation in view of the Slager Article. ArthroCare again argues that the Slager Article does not explicitly disclose applying energy to a body structure of a patient. However, for the reasons shown above, this argument must fail.[23]

ArthroCare also argues that the Slager Article does not explicitly disclose the location of the return electrode. (D.I. 467 at 40). But ArthroCare is incorrect, since Slager clearly discloses that the aortic segments were only 7 cm. long, whereas the electrodes were spaced up to 10 cm. apart. (DTX-65 at 1382-83). As such, a return electrode that was up to 10 cm. away from the active electrode could not possibly have been in contact with tissue that was only 7 cm. long. Moreover, contrary to ArthroCare's argument, Dr. Taylor never testified that he could not determine the location of the return electrode. (D.I. 416 at 1414-18). In fact, ArthroCare never even asked him about the return electrode in the *in vitro* tests, which Dr. Taylor relied upon. (*Id.*).

Thus, ArthroCare has not overcome Smith & Nephew's *prima facie* case of anticipation based on the Slager Article, and the Court should grant JMOL on this issue as well.

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[22] Had Doss used an unusual generator such as the custom-built square wave generator of the Slager Article as ArthroCare suggests, it would have had to have been disclosed to satisfy the best mode requirement.

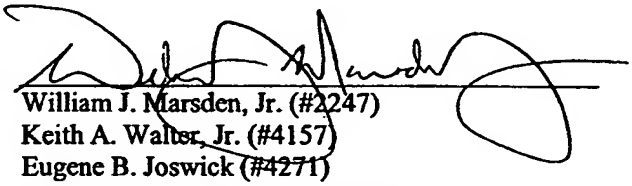
[23] In granting Smith & Nephew's reexamination request for the '592 patent, the Examiner misinterpreted the Slager Article as not anticipating. (Joswick Dec. Ex. C at 3). However, ArthroCare is under a continuing duty to apprise the PTO of material information disclosed during these proceedings (*Id.* at 4-5; 37 CFR 1.555), including Mr. Eggers' testimony that he reduced the claimed invention to practice in a bowl outside the human body.

III. CONCLUSION

For all the foregoing reasons, as well as the reasons set forth in Smith & Nephew's Opening Brief, Smith & Nephew respectfully requests that the Court enter JMOL that the '882 certificate of correction is invalid, that the accused products do not infringe the asserted claims, that the asserted claims of the '536 and '592 patent are anticipated by the prior art, and that the asserted claims of the '882 patent are not enabled and are anticipated by the prior art.

Dated: August 14, 2003

FISH & RICHARDSON P.C.

By: 

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CERTIFICATE OF SERVICE

I hereby certify that on this 14th day of August, 2003, a true and correct copy of SMITH & NEPHEW'S REPLY BRIEF IN SUPPORT OF ITS RULE 50(b) MOTION FOR JUDGMENT AS A MATTER OF LAW was caused to be served on the attorneys of record at the following addresses as indicated:

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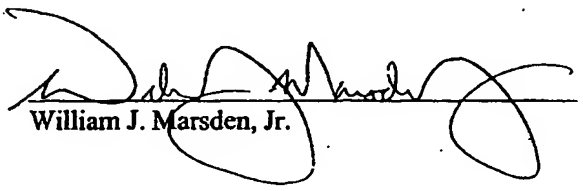

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